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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/981,665	11/05/97	CIPKOWSKI	S 3000

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EXAMINER

GRUN, J

ART UNIT

PAPER NUMBER

1641

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/981,665**

Applicant(s)  
**CIPKOWSKI**

Examiner  
**James L. Grun, Ph.D.**

Group Art Unit  
**1641**



☒ Responsive to communication(s) filed on 5 Oct 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) 1-4 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 5-15 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The drawings are not objected to by the draftsperson as set forth on the attached PTO Form

5 948. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

Applicant's election with traverse of Group II, claims 5-15 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that all of the claims are drawn to a single inventive concept wherein the subcombinations of the inventive test kit could not be used with other like structures without considerable modification and that different classification of the subcombinations should not constitute a basis for requiring restriction. These are not found persuasive because, for reasons of record, there is no "special" technical feature to link the inventions as claimed in technical relationship, the combination as claimed does not even require the particulars of the immunoassay test card subcombination, and the subcombination has separate utility. Separate classification and/or a different field of search are *prima facie* evidence of a serious burden on the Examiner.

15 The requirement is still deemed proper and is therefore made FINAL.

Claims 1-4 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 4.

The disclosure is objected to because of the following informalities: page 4, line 18, --card--  
20 is misspelled; page 11, line 11, --ply-- is misspelled. Appropriate correction is required.

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Claims 5-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 5-15, “the size and shape of a business card” lacks antecedent basis and is vague and indefinite as to what size and shape are encompassed. Further, “the outline” lacks antecedent basis. It is not clear what is encompassed by a “particular” drug of abuse.

In claims 5-15, “A multiple drug test card...” should be --The multiple drug test card--.

In claim 7, “the longer dimension” lacks antecedent basis.

In claim 9, “said first side surface” lacks antecedent basis.

In claim 10, the interrelationships of the components are entirely unclear, e.g. it appears that the test strips are on the inside of the thin flat member and not adhered to a first side thereof as claimed in claim 5. It is believed that Applicant intended the thin flat member as comprised of two laminated sheets covered by the third sheet.

In claims 11 and 13, “the thickness” and “the sample and test portions” lack antecedent basis. The interrelationships of the components are entirely unclear, e.g. it is not clear how the test strips are adhered on a first side of the thin flat member if the thin flat member has slots which may go entirely through the member and the strips contact the second member adhered to the rear surface of the thin flat member (see e.g. Fig. 10).

In claim 12, “said second and third thin flat members” lack antecedent basis. It is believed Applicant intended the claim to depend from claim 11 rather than claim 5.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10 (c) Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 5-8 and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee-Own et al (US 5,500,375) in view of Sun et al (US 5,238,652) and Davis (US 5,119,830).

15 Lee-Own et al disclose laminated immunochromatographic devices for detection of analytes, including drugs of abuse (e.g. columns 5 or 8). Immunochromatographic assay means, such as impregnated nylon membrane strip(s) (e.g. column 5), are laminated between sealing means and support means, such as adhesive films or plastic sheets (columns 7-9). The reference teaches transparent plastic for the sealing/support means, thereby exposing the membrane strip(s) for viewing. Lamination would be expected to provide a slot-like "recess" in the films and/or sheets housing the strip(s) as depicted in any of Figs. 2, 3, 9, or 11. Multiple membrane strips may be configured in a single device to allow for multiple assays (e.g. column 7, lines 21-23). The device may be incorporated into a sample collection vessel such as a urine collection vessel (e.g. column 8). In use, the end of the membrane strip(s) is/are exposed by cutting the laminate or peeling off a protective cover and the membrane(s) contacted with sample by dipping into, immersion into, or application

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thereto of sample. In contrast to the invention as instantly claimed the reference does not specify parallel placement of the multiple membrane strips and does not specify the size and shape of the device.

Sun et al teach membrane strips for competitive immunoassay of drugs of abuse and that analytical test devices incorporating the strips for such drug of abuse analytes may be configured in a parallel arrangement for simultaneous testing of multiple analytes (e.g. Fig. 3), at least five analytes in a single device being preferred (e.g. column 2).

Davis teaches an analytical specimen cup having a chemical test "strip" with a plurality of "pads" for multiple analytes, in one embodiment the "strip" being the size and shape of a card (see e.g. Figure 6) having the multiple analyte "pads" arranged in parallel.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have configured the multiple membrane strips contemplated by Lee-Own et al in their device in parallel arrangement because such arrangement is conventional in the art as taught by Sun et al or Davis, such arrangement is well within the skill of an ordinary practitioner, and such arrangement would have been expected to simplify exposure of the membrane strips in the device by allowing a single cut of the laminated layers to expose all of the strips for use. It would have been further obvious to one of ordinary skill in the art at the time the instant invention was made to have provided the multiple membrane strip device of Lee-Own et al, as modified, in the size and shape of a card because the use of adhesive films or plastic sheets as the sealing/support means by Lee-Own et al would implicitly provide such a size and shape to the device, the laminated device can be die-cut

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to any required dimension, and one would have been motivated to provide such a size and shape to the device to facilitate incorporation of the device into a urine collection vessel either of conventional design as disclosed in Lee-Own et al or of a design such as that of Davis.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the  
5 absence of evidence to the contrary.

Claims 5-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sun et al (US 5,238,652) in view of Boger et al (US 4,518,565) <sup>and</sup> (either of) Davis (US 5,119,830) or Lee-Own et al (US 5,500,375), and any of Huang et al (US 5,712,172) or Norell (US 5,441,698).

As set forth previously, Sun et al teach membrane strips for competitive immunoassay of  
10 drugs of abuse, that simultaneous testing of at least five drug of abuse analytes is desirable (e.g. column 2), and that analytical test devices incorporating the strips for such drug of abuse analytes may be configured in a parallel arrangement for simultaneous testing of multiple analytes (e.g. Fig. 3). In contrast to the invention as instantly claimed, the reference teaches moisture impervious housing(s), such as welded plastics, for supporting the membrane strips rather than alternative  
15 supports.

The teachings of Davis or Lee-Own et al are as set forth above.

Boger et al teaches a holder for dip-and-read reagent test strips. The holder can be constructed of any suitable material including coated cardboard and comprises at least a base member, which may have ridges or other means which facilitate the preferred parallel alignment of the strips,

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and a top member, which has openings to expose the strips (see e.g. columns 3-4). The members may be provided separately or as a foldable assembly. It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have formed the ridges, defining slots, as taught in Boger et al by any conventional means because one of ordinary skill would have expected a conventional means such as lamination of multiple layers, molding, or cutting, to form the desired ridges and slots therein. One would have had ample motivation to select from among conventional known techniques with an expectation of success. The strips may extend beyond the holder (Figs.) or the holder can be made long enough to accommodate the strips in their entirety (column 4). The holders may be either disposable or reusable and may be used for storage of test strips after their use for testing. It would have been an obvious matter of design choice to have adhered the test strips to the device in those embodiments where either a disposable or storage holder were contemplated, as is conventional in the art, to prevent shifting of the test strips in the holder device.

Huang et al teach sandwiching, by lamination, of an immunochromatographic device between a backing material and a plastic covering material to obviate the need for a plastic housing. The covering material partially covers the device or encompasses one or more openings or holes to provide an exposed sample receiving region (e.g. Figs. 1 and 4) and, if not of a clear material, an additional window, gap, or hole is provided in the covering for results viewing. Illicit drugs are suggested analytes for detection with the invention (see e.g. column 4). Although not specifically taught in the reference, it would have been obvious to have housed multiple devices for a number of analytes in a single assembly as is conventional in the art.



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Norell teaches foldable cardboard-like (e.g. column 3) supports for test strips having windows and/or wells (i.e. slots).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have supported the test strips of Sun et al on any known and conventional alternative support, such as any of those taught by Boger et al, Huang et al, Lee-Own et al, or Norell because one would have had ample motivation to select from known and conventional alternative support components with the expectation that the components would perform the desired support function. It would have been further obvious to have provided the support as foldable or comprised of multiple layers, and as having various slots or windows for sample application or viewing, as is conventional as taught by any of Boger et al, Huang et al, Lee-Own et al, or Norell. As regards incorporating slots within the support for aligning of the test strips, it would seem a matter of obvious design choice to have provided such slots as slots are a known means of precisely aligning components, as taught in Boger et al. It would have been further obvious to one of ordinary skill in the art at the time the instant invention was made to have provided the multiple membrane strip device of Sun et al, as modified, in the size and shape of a card because one would have been motivated to provide such a size and shape to the device to facilitate insertion or incorporation of the device into a urine collection vessel either of conventional design as disclosed in Lee-Own et al or of a design such as that of Davis.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Galloway et al (US Patent No. 5,403,551) teach (see e.g. Figs. 1-5) a plurality of chromatographic strips (five are shown, but a greater or smaller number of strips may be used (column 4)) for analyzing a sample, such as drug-specific immunoassay chromatographic strips for analyzing a urine sample (columns 3-4), disposed in a generally parallel relationship on a cover, comprising a thin flat rectangular member of a size permitting insertion into the depicted collection container, along a longitudinal axis of the sample collection container. Ribs may be provided for positioning and separation of the strips in what would appear to be slots (see e.g. Fig. 4).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to James L. Grun, Ph.D., Technology Center 1600, Group 1640, Art Unit 1641, whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James C. Housel, SPE, can be reached on (703) 308-4027. The fax phone numbers for official communications to Group 1640 are (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
James L. Grun, Ph.D.  
November 19, 1998

  
JAMES C. HOUSEL 11/21/98  
SUPERVISORY PATENT EXAMINER